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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,937	11/16/2005	Jacques Latrille	065691-0385	9440

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/523,937	LATRILLE ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/7/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending.

Information Disclosure Statement

The information disclosure statement filed on Feb. 7, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 1-7 are objected to because of the following informalities: There are missing articles in these claims. Each claim should start with an article and also an article "a" is missing before "monomer form" in 1st line of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents recites the limitation "the said 6-keto-prostaglandin..." in 5th line. There is insufficient antecedent basis for this limitation in the claim.

The phrase "... high ionic strength of the destabilase complex, ..." in claim 1 and its dependents does not clearly point out and distinctly claim the subject matter. It appears that this is a step for elution of a destabilase complex using a buffer with high ionic strength. However, the current claim reads as if the destabilase complex has high ionic strength.

The term "it" in 10th line of claim 1 and its dependents does not clearly point out and distinctly claim the subject matter. "It" could be a destabilase complex, an elution buffer, 6-keto-prostaglandin antibodies, medicinal leeches, or liposome.

Claim 5 provides for the use of a destabilase complex, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition

of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nikonov et al. (1999).

Claims 1, 2 and 4 are drawn to a stable destabilase complex in a monomer form (claim 1); a pharmaceutical composition comprising the destabilase complex and a pharmaceutically acceptable vehicle (claim 2); a limitation to the destabilase complex being a medicine (claim 4);

Nikonov et al. (1999) teach a stable destabilase complex isolated from medicinal leech as a monomer, which can be aggregating (polymer) into a natural liposome. Nikonov et al. also teach steps to prepare the destabilase complex, which comprise affinity chromatography and elution steps (see Abstract; Introduction, p.102; Materials and Methods, p.103; Discussion, p.105).

Nikonov et al. also teach the destabilase complex, referred as a drug (medicine) (p. 103, Materials and methods), can be used in injection to animals and this complex

provides prophylactic antithrombotic action (see Abstract and Introduction) and it is dissolved in a Tris-HCl buffer (pharmaceutically acceptable vehicle).

Claim 1 is a product-by-process claim; claims 2-7 depend from the said claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established.

We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Therefore, the process of making the destabilase complex such as the steps of affinity chromatography and elution in the claims do not have limitations.

Although Nikonov et al. do not disclose the biochemical property of the complex such as an antithrombin activity of at least 700 ATU/mg, a plasma recalcification time of at least 800 APC/mg, a fibrinolytic activity of at least 40 mm^2/mg and an immunomodulating activity, it is inherent that the destabilase complex of the reference possess the same biochemical property as the destabilase complex of the claimed invention because both complexes are from the same source (medicinal leech) and the same purification steps (affinity chromatography and elution).

Thus, the reference anticipates the claimed subject matter.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Greff (FR 2603188) or Nikonov et al. (RU 2113843C1).

Claim 3 is drawn to a cosmetic composition comprising the destabilase complex.

Greff teaches a cosmetic composition containing medicinal leech extract which is obtained from the head of the leech or from the entire animal.

Nikonov et al. teach a cosmetic agents separated from medicinal leech as additive having anti-inflammatory and proteolytic activity.

Although Greff or Nikonov et al. do not teach the property of the complex, since the destabilase of the references was isolated from leech and therefore possess the same property as the destabilase complex of the current application, the destabilase of the references inherently has the same property and function as the destabilase complex of the current invention.

Claim 1 is a product-by-process claim; claims 2-7 depend from the said claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bini (US 6,020,181) in view of Nikonov et al. (1999).

Claims 6 and 7 are drawn to an implantable medical prosthesis in which at least part of the prosthesis being covered with a cladding and the cladding comprising the destabilase complex (claim 6); a limitation to the implantable medical prosthesis being a stent support (claim 7).

Bini teaches a stent coated with an enzyme inhibiting thrombus formation and an example of such enzyme being obtained fibrinolytic enzymes from leeches with a reference of Zavalova et al., which discloses a destabilase (see column 3, lines 15-16; column 6, lines 46-49). The limitation of "cladding" is considered as any layer such as a coating. Bini teaches that a fibrinolytic enzyme can be employed as a coating (see column 10, line 16).

Nikonov et al. teach the destabilase complex isolated from leeches and having a fibrinolytic activity.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the destabilase complex of Nikonov et al. in the stent taught by Bini.

The skilled artisan would have been motivated to make such a modification because Bini teaches a stent coated with a fibrinolytic enzyme and that such enzyme is present in the destabilase complex of Nikonov et al. Furthermore, Bini discloses the fibrinolytic enzyme preferably in combination with a thrombolytic agents to improve thrombolytic and fibrinolytic therapy (see Abstract). Since the destabilase complex of Nikonov et al. has both fibrinolytic activity and anti-thrombin (thrombolytic) activity provided by hirudin in the complex, a person of ordinary skill in the art would have been motivated to use the complex of Nikonov et al. in the stent support of Bini.

The person of ordinary skill in the art would have had a reasonable expectation of success in the use of the complex of Nikonov et al. as a coating of a stent taught by Bini because the stent of Bini can successfully have a coating of enzymes having a thrombolytic and a fibrinolytic activity.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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